sybron dental specialties K091091

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

OCT 14 2009

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz- Contact Person

Date Summary Prepared: October 2009

Device Name:

- Trade Name – ***SONICfill 2010***
- Common Name – Tooth shade resin material
- Classification Name – Material, Tooth Shade, Resin, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Produits Dentaires Pierre Rolland, *Expasyl Power Applicator(K051933)*

Device Description:

The *SONICFill 2010* is an air driven dental delivery system intended to dispense Metamorphosis, a dental restorative resin, directly into dental cavities. The device allows fast and easy extrusion of the composite, which is held in single-dose cartridges (tips). The tips are connected to the device via a screw thread. The device is attached to the dental unit through a coupling and a hose. It is powered via compressed air supplied by the operative unit. The device is switched on and off through the footswitch of the dental unit and the power output can be adjusted through a regulating ring located on the device. The devices can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *SONICFill 2010* is a dental delivery system intended to be used to dispense Metamorphosis, a dental restorative resin, directly into dental cavities.

Substantial Equivalence:

The *SONICfill 2010* dental delivery system is substantially equivalent to other legally marketed devices in the United States. *SONICfill 2010* functions in a manner similar to and is intended for a similar use as the *Expasyl Power Applicator* marketed by Produits Dentaires Pierre Rolland.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Claudia Ortiz
Compliance Director, Regulatory Affairs & Quality Assurance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

OCT 1 4 2009

Re: K091091
Trade/Device Name: SONICfill 2010
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: September 22, 2009
Received: September 23, 2009

Dear Ms. Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091091

Device Name: *SONICfill 2010*

Indications for Use:

The *SONICFill 2010* is a dental delivery system intended to be used to dispense Metamorphosis, a dental restorative resin, directly into dental cavities.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulley for MSR

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K091091